



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0477]

Center for Devices and Radiological Health: Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Standard Operating Procedure (SOP) for Level 1, Immediately in Effect (IIE) Guidance Documents on Premarket Data Issues. The SOP describes the Center for Devices and Radiological Health's (CDRH's or the Center's) process to clarify and more quickly inform stakeholders when CDRH has changed its expectations relating to, or otherwise has new scientific information that could affect data submitted as part of an Investigational Device Exemption (IDE) or premarket submission, including a Premarket Notification (510(k)), a Premarket Approval (PMA), a Humanitarian Device Exemption (HDE), or combination products containing a device constituent part for which CDRH has jurisdiction that needs to be disseminated in a timely manner.

DATES: Submit either electronic or written comments on this SOP at any time. General comments on Agency SOP documents are welcome at any time.

ADDRESSES: See the SUPPLEMENTARY INFORMATION section for information on electronic access to the SOP. Submit electronic comments on the SOP to

<http://www.regulations.gov>. Submit written comments to the Division of Dockets Management

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678, [Philip.desjardins@fda.hhs.gov](mailto:Philip.desjardins@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Task Force on the Utilization of Science in Regulatory Decision Making (the Task Force) published a Preliminary Report and Recommendations in August 2010. In the report, the Task Force noted that when new scientific information changes CDRH's regulatory thinking, it has been challenging for the Center to communicate the change and its basis to all affected parties in a meaningful and timely manner. The Task Force recommended that the Center make use of more rapid tools for broad communication on regulatory matters, including establishing a standard practice for communicating to all manufacturers of a particular group of devices for which the Center has changed its regulatory expectations on the basis of new scientific information.

Currently, manufacturers typically learn of changes CDRH implements regarding what data or how to gather specific data in support of an IDE or premarket submission at the time of or soon after a decision is made through individual engagement with the Center, often not until after they have prepared that submission. Reviewers may implement these changes, such as requesting new clinical data or using a new test method, on a case-by-case basis, with immediate supervisory concurrence when it is necessary to protect the public health. For example, a reviewer may request that sponsors test their implantable device for durability because new data

demonstrate that this type of device is prone to failure due to premature wear and tear of the technology. Although CDRH may issue a detailed guidance document, the document may not be published until a year or more after a Branch- or Division-level decision has been made to request the information because of the resource constraints in developing guidance documents.

CDRH believes that timely communication with industry about changes in premarket regulatory expectations is important. FDA's Good Guidance Practices regulation provides a mechanism for communicating and implementing certain changes in regulatory expectations quickly, without requiring prior public comment. Under 21 CFR 10.115(g)(2), FDA may issue a Level 1, IIE Guidance Document when prior public participation is not "feasible or appropriate." Under these circumstances, CDRH intends to use the procedures described in § 10.115(g)(2) to issue guidance documents addressing changes in premarket regulatory expectations. CDRH has developed this SOP to facilitate issuance of such guidance documents.

On September 5, 2013 (78 FR 54655), CDRH issued a draft SOP that meets the Center's needs and addresses concerns raised regarding an original "Notice to Industry Letters" proposal (July 21, 2011, 76 FR 43693). Interested persons were invited to comment by October 21, 2013. Three comments were received with suggestions pertaining to the administrative process and policies regarding IIE guidances. In response to these comments, FDA revised the SOP to clarify the processes and policies as appropriate. This document will supersede the "Draft Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues" issued on September 5, 2013.

## II. Electronic Access

Persons interested in obtaining a copy of the SOP may do so by using the Internet. The Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on

Premarket Data Issues is available at

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf>. The SOP is also available from <http://www.regulations.gov> and can be located using the docket number found in brackets in the heading of this document.

### III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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